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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE
1141 Central Parkway
Cincinnati, OH 45202-1097

June 23, 1997

WARNING LETTER
CIN-WL-97-419

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harry M. Bickelman, President
Spector Inc.
5674 Shepherdsville Rd.
Louisville, KY 40228

Dear Mr. Bickelman:

The Food and Drug Administration (FDA) conducted an inspection on June 5 and 6, 1997, of your firm which manufactures Tomax, a computer controlled tomography imaging system. This is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection found this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The following deviations from Device GMP's were documented:

- Failure to establish and maintain a quality system
- Failure to conduct planned and periodic audits of the quality system in accordance with written procedures
- Failure to establish a formally designated unit to review, establish, and maintain written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness or performance of the device and determine whether or not an investigation is necessary
- Failure to document, review, approve, implement and validate changes to components, labeling, packaging or manufacturing process specifications
- Failure to maintain an approved Device Master Record which contains applicable specifications
- Failure to maintain a Device History Record for individual finished devices that have been

released for distribution

- Failure to document and ensure that finished devices meet all specifications prior to distribution

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

LEB/mjj